UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE CARACO PHARMACEUTICAL LABORATORIES, LTD., SECURITIES LITIGATION	)	Case No. 2:09-cv-12830-AJT-DAS CLASS ACTION

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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I. INTRODUCTION

Defendants' Motion to Dismiss the Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws ("Motion"), employs vitriol and a wholesale re-characterization of the consolidated amended complaint's allegations to evade the fact that Lead Plaintiff Tushar Amin ("Lead Plaintiff"), Plaintiff Kevin Koziatek, and Plaintiff Jonathan Wilkof (collectively "Plaintiffs"), have sufficiently pled that defendants made knowing and/or reckless misrepresentations and omissions concerning, among others, Caraco's compliance with the United States Food and Drug Administration's ("FDA") current Good Manufacturing Requirements ("cGMP").[1]

June 25, 2009 (the last day of the Class Period), was the day of reckoning for Caraco and the culmination of defendants' misrepresentations and material omissions concerning Caraco's problems with, among other things, manufacturing generic pharmaceutical tablets of varying size and weight. At the request of the FDA, U.S. Marshals raided Caraco's Michigan facilities – seizing drug products manufactured by Caraco in Farmington Hills and Wixom, as well as ingredients held at those facilities – citing "Caraco's continued failure to meet the FDA's [cGMP] requirements, which assure the quality of manufactured drugs" and indicated that through the seizure, "the FDA [was] seek[ing] to immediately stop the firm from further distributing drugs until there [was] an assurance that the firm complies with good manufacturing requirements." ¶134.[2] Specifically, the FDA further noted that "[s]ince January 2009, Caraco has initiated voluntary recalls of drug products to protect the public from potentially defective medications" as the "recalls involved manufacturing defects,

[1] The Defendants include Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or the "Company"), its former Chief Executive Officer ("CEO") and Director Daniel H. Movens ("Movens"), its Chairman of the Board of Directors Dilip Shanghvi ("Shangvi") (along with Movens, the "Individual Defendants"), and its controlling shareholder Sun Pharmaceutical Industries, Ltd. ("Sun Pharma") (collectively, "defendants").

[2] All "¶__" are references to the Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws ("Complaint"), which asserts claims under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, on behalf of purchasers of Caraco's securities from May 29, 2008 and June 25, 2009, inclusive (the "Class Period").

including oversized tablets and possible formulation error." *Id.* This news was, to say the least, disturbing. Consumers of the Company's products and investors of the Company's securities finally learned the full extent of rampant and systematic manufacturing and regulatory problems at the Company.

Realizing the strength of plaintiffs' allegations, defendants ignore the well-established principle that for purposes of a motion to dismiss, courts must accept the allegations as true. Instead, defendants repeatedly and improperly challenge the allegations by characterizing them as "simply untrue," "incredulous[]," "simply not believable," and "wholly unreliable." A jury will have an opportunity to assess the weight of the evidence in this case at trial. Despite defendants' arguments to the contrary, it is not the function of the Court to make such credibility determinations at the pleading stage. As set forth herein, the Complaint adequately pleads each element of the claims alleged. The Court should deny Defendants' motion.

II. STATEMENT OF ISSUES PRESENTED

A. Whether Plaintiffs Have Adequately Alleged That Defendants Made Materially False and Misleading Statements to Pursue a Claim Under Section 10(b) of the Exchange Act When Defendants Represented that the Company Was Compliant with Manufacturing Regulations and Minimized the Risks Associated with Regulatory Compliance;

B. Whether Plaintiffs Have Adequately Alleged That Defendants Acted With Knowledge or Acted Recklessly in Making Materially False and Misleading Statements Pursuant to Section 10(b) of the Exchange Act Where Divergence Between Negative Internal Reporting and Defendants' Positive Statements to the Market, Defendants' Disregard of the Most Current Factual Information, the Statements of Confidential Witnesses Defendants' Benefit from the Fraud, the Proximity of Defendants' Positive Statements to Revelation of the Truth, the Core Operations Inference, the Resignations of Key Executives, Defendants' Self Motivation in Saving Their Salaries and Bonuses, and Defendants' False Sarbanes-Oxley Certifications Collectively Raise a Strong Inference of Scienter; and

C. Whether Plaintiffs Have Adequately Alleged That Certain Defendants Are Liable as Control Persons Pursuant to Section 20(a) of the Exchange Act When They Possessed Both the Power and the Authority to Exercise Control Over Defendants That Are Primarily Liable Under Section 10(b) or When They Controlled a Majority of the Shares of the Company.

III. CONTROLLING OR MOST APPROPRIATE AUTHORITY

Cases

Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009)

Basic, Inc. v. Levinson, 485 U.S. 224 (1988)

Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)

City of Monroe Employees Retire. Sys. v. Bridgestone Corp., 399 F.3d 651 (6th Cir. 2005)

Dura Pharms., Inc. v. Broudo, 544 U.S. 336 (2005)

Ernst & Ernst v. Hochfelder, 425 U.S. 185 (1976)

Frank v. Dana Corp., 547 F.3d 564 (6th Cir. 2008)

Helwig v. Vencor, Inc., 251 F.3d 540 (6th Cir. 2001)

In re America Service Group, Inc., No. 3:06-0323, 2009 WL 1348163 (M.D. Tenn. Mar. 31, 2009)

In re Cabletron Sys., 311 F.3d 11 (1st Cir. 2002)

In re Daou Sys., Inc., 411 F.3d 1006 (9th Cir. 2005)

In re Huffy Corp. Sec. Litig., 577 F. Supp. 2d 968 (S.D. Ohio 2008)

In re Immune Response Sec. Litig., 375 F. Supp. 2d 983 (S.D. Cal. 2005)

In re Par Phar., Inc. Sec. Litig., 733 F. Supp. 668 (S.D.N.Y. 1990)

In re ProQuest Sec. Litig., 527 F. Supp. 2d 728

Lormand v. US Unwired, Inc., 565 F.3d 228 (5th Cir. 2009)

Makor Issues & Rights, Ltd. v. Tellabs Inc., 513 F.3d 702 (7th Cir. 2008)

No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920 (9th Cir. 2003)

PR Diamonds, Inc. v. Chandler, 364 F.3d 671 (6th Cir. 2004)

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 127 S. Ct. 2499 (2007)

Statutes: 15 U.S.C. §78u-4(b)(1)(B); 15 U.S.C. §78u-5(c)(1)(A); 15 U.S.C. §78u-5(c)(1)(B); 15 USC §78u-4(b)(1); **Regulations:** 17 C.F.R. §240.10b-5

IV. STATEMENT OF FACTS

Defendant Caraco primarily develops, manufactures, markets and distributes generic and private-label pharmaceuticals to wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers throughout the U.S and Puerto Rico. ¶2. Caraco's 76% majority owner is Sun Pharma, an international pharmaceutical company headquartered in India. ¶3. With Sun Pharma's backing, Caraco had begun to compete with much larger companies in the highly-competitive generic drug market. *Id.*[3] In fact, between fiscal 2007 (which ended March 31, 2007) and fiscal 2008, Caraco's sales volume tripled, from $117 million to $350 million. *Id.*

A. Caraco's "Recurring Product Variability Issues"

After recalling seven lots of Mertformin HCL Tablets, USP, 1000mg, in January 2008 -- which according to the FDA, were recalled due to some tablets being undersized or oversized resulting in the patient not receiving the expected dose ¶59 – in a June 10, 2008, filing with the SEC Caraco assured investors that "[t]he product recall announced by the FDA was limited to a single compression machine malfunction, and affected two lots" but that Caraco "chose to recall seven lots that were produced on that particular machine as an additional safeguard." ¶102. A "single" machine, however, was not to blame, as before and throughout the Class period Caraco actually had wide-scale systematic manufacturing problems that were yielding over and undersized tablets affecting far more than "two lots." ¶103(a). Throughout the Class Period, the Company received numerous customer complaints regarding this problem for tablets that were produced during the Class Period. ¶¶168-69 (outlining specific

[3] With Sun Pharma's financial and research and development support, the latter including five-year technology transfer agreements in 1997 and 2002, Caraco has been able to submit several dozen applications to the FDA to be approved to manufacture and sell generic formulations for some of the most widely-purchased drugs on the market. ¶3. In addition, Caraco entered into agreements with Sun Pharma to act as a distributor of Sun Pharma's products. *Id.*

customer complaints). Quality inspectors frequently discovered tablets that were too thick/thin, as well as tablets that were broken and/or chipped. ¶97(a).[4]

Defendants, including Defendant Movens, were well aware of the severity of this problem. A December 22, 2008, letter from the FDA to Defendant Movens specifically reiterated to him that "there is a real problem regarding your processes that are yielding tablets of varying sizes" and "[t]he fact that...there are a number of customer complaints regarding tablet size for a variety of products is disconcerting. Validated processes should yield product of consistent quality. This issue needs to be resolved as it has been going on quite some time." ¶76. Moreover, the Company never reported to investors that by November 2008, the Company had established a "variability study"[5] to address the problem, nor that by February 19, 2009, the problem was so bad that the Company had to essentially halt internal research and development ("R&D") so the R&D team could help address the issue.[6]

The "recurring product variability issue" later partially revealed itself on March 31, 2009, when Caraco disclosed that it had to recall certain tablets manufactured by the Company because the tablets might have differed in size and therefore could have more or less of the active ingredient. ¶82. This news sent Caraco's shares down $1.03 per share, more than 22%, to close on March 31, 2009, at $3.52 per share, on unusually heavy volume. ¶125. Caraco again recalled products on April 17, 2009, ¶127, and on June 8, 2009. ¶86.

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[4] Numerous other witnesses also detailed the wide-spread issues with over and undersized tablets during the Class Period. *See e.g.*, ¶93(b) (noting that tablet variation was a serious problem and providing example where in one set of tests weighing over 900,000 tablets of Digoxin, a Class 2 drug that could be lethal at the wrong dosage, approximately 2% were found to be of the wrong size – an incredibly high ratio of defective product for pharmaceuticals).

[5] *See* ¶88 (June 19, 2009, letter to the FDA conceding existence of "reoccurring variability product issues" and that the Company had to establish a "variability study" in November 2008 to address the issue, and noting that most reoccurring variability issues were occurring with the Company's Metoprolol, Clonazepam, Digoxin, and Metformin products).

[6] *See* ¶79 (February 19, 2009, letter from Defendant Movens to the FDA stating that Caraco had "stopped most of our internal research and development activities to allow the R&D team to act as additional support for tech services" and were "analyzing the trends for recurring product anomalies and are taking appropriate action as necessary to eliminate any remaining issues with product quality").

The Defendants' Brief largely glosses over and/or ignores Caraco's "recurring product variability issue" (*i.e.*, Caraco's inability to produce pills of a consistent size and weight). This noticeable absence is for good reason. As the FDA's website explains:

> cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA). cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. ***Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.*** This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. ***This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.***

(Emphasis added).[7] The mere existence of such a pervasive product variability issue, which was well-known to Defendants, essentially means that the Company was neither cGMP compliant nor could any defendant "believe" that Caraco was "substantially compliant."

B. Caraco's Grossly Non-Compliant Manufacturing Operations

In addition to the product variability issue, Caraco's operations during the Class Period were rife with systematic manufacturing problems and severely non-compliant with cGMPs. *See e.g.*, ¶103(b)-(c), 113, 121, 130. In July 2008, there were approximately 1,000 Standard Operating Procedures ("SOPs") that one former employee indicated needed to be updated, and in some cases, SOPs which had not been updated in 12 to 14 years. ¶93(l). In 2008 alone, there were over 1,000 incidents of problems, for example weight variation, contaminants such as hair found in the product, or tablets that were too thick/thin. ¶93(a)-(l).

In the face of rampant manufacturing problems and utter cGMP deficiencies, Caraco was recklessly driving production increases that directly belied defendants' claims to be proactively growing the Company's business "appropriately." ¶103(c). Witnesses recall

[7] *See* FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited May 27, 2010)

production problems due to the intense pressure to make more drugs despite the lack of infrastructure to do so and that every time there was an issue, management wanted to bypass the issue so that they could get production. ¶¶92, 94(a). When a product did not meet the in-house specifications, the manufacturing personnel would release the product anyway as management's attitude was to "get the tablets out the door." ¶93(d). Indeed, machines were not even allowed to be shut down when updating SOPs. *Id.*[8] Moreover, it was readily apparent that the Company's employees lacked the necessary training to perform their assigned functions and poor infrastructure made it almost impossible to properly train employees to use the "ERP" system to track raw materials. ¶101.

After stating "we believe we remain substantially complaint" with cGMPs in a filing with the SEC on June 10, 2008, the very next day, on June 11, 2008, the FDA issued a Form FDA 483 to Caraco, addressed to defendant Movens, listing fourteen observations regarding Caraco's manufacturing practices, many of which concerned failures in fundamental operating procedures regarding the manufacture of drugs for human consumption. ¶60. Nevertheless, in filings with the SEC on July 25, 2008, and October 24, 2008, with regard to the Form FDA 483, Caraco downplayed the event and reassured investors that "[t]he Company has responded accordingly and we believe we remain substantially compliant." ¶¶106, 112.

C. The FDA Warning Letter

On November 3, 2008, Caraco issued a press release announcing that it had received a warning letter from the FDA. ¶114. Caraco's November 3, 2008, announcement that it had received the Warning Letter was a partial materialization of the undisclosed risks inherent in pushing rapid drug production at the expense of quality and regulatory compliance and revealed: that at the time its prior statements were made, Caraco had not been substantially cGMP compliant; that the Company had not responded to the FDA's observations in the June 2008 Form 483 accordingly; that the Company had not remedied previous observations from

[8] Despite the existence of these problems, production and output were increased. One former employee indicated that Defendant Shanghvi and Sun Pharma excerted control over and set targeted production goals which were constantly increased. ¶98(b)

the FDA; and that as a result, the Company could face regulatory sanctions. ¶9. On this news, over the next three days, shares of Caraco declined by $2.26 per share, or 22.22%, to close on November 5, 2008, at $7.91 per share, on unusually heavy volume. ¶10.

D. Caraco Claims to Have Addressed the Issues Appropriately

By letter dated November 24, 2008, Defendant Movens, on behalf of Caraco, responded to the FDA's Warning Letter, ¶74, and Caraco issued a press release announcing that the Company "believes it has addressed the concerns in the warning letter appropriately." ¶118. Around this time, in December 2008, Sun Pharma installed two senior managers at Caraco: Sandeep Mehta as Director of Manufacturing and Sunil Ajmera as Vice President of Manufacturing, and both pushed for production "over anything else." ¶93(h)-(k).[9]

Despite receiving yet another FDA Form 483 on December 22, 2008, containing five observations, ¶75, on January 29, 2009, the Company issued a press release wherein Defendant Movens once again allayed concerns by stating that "we believe we remain substantially compliant" and that "the Company's sales of current products continue in the normal course of business" and "[w]e continue to add products to our portfolio through Sun Pharma and its affiliates that we will launch into the US," ¶120.[10] In a February 3, 2009, filing with the SEC, the Company downplayed the December 22, 2008, Form FDA 483 and reassured investors that "[t]he Company believes it has responded appropriately to the FDA's concerns, and corrective measures have been put into place." ¶122.

E. Caraco Recalls Certain Products

Caraco provided the FDA on February 11, 2009, with two Field Alert Notifications regarding its Metoprolol Tartrate Tablets for two different dosages, both of which indicated that "a market complaint" was received on "January 28, 2009 indicating that tablets of different

[9] A witness explained that while both Mehta and Ajmera ostensibly reported directly to Movens it appeared that Mehta and Ajmera, as agents of Sun Pharma, were running Caraco. ¶93(h)-(k).

[10] In reality, however, Caraco later admitted that "[w]ith deliberate efforts, since December 15, 2008, we have slowed down new product development and technology transfer activities for continuous focus on cross-functional training and resolution of process and product related discrepancies." ¶87.

sizes were found in" certain lots. ¶78. Approximately one week later, in a February 19, 2009 letter to the FDA, Defendant Movens stated that Caraco had "stopped most of our internal research and development activities to allow the R&D team to act as additional support for tech services" and that they were "analyzing the trends for recurring product anomalies and are taking appropriate action as necessary to eliminate any remaining issues with product quality." ¶79.

Caraco further disclosed on March 31, 2009, that it had to recall certain tablets manufactured by the Company as the tablets might have differed in size and therefore could have more or less of the active ingredient. ¶82. This news sent Caraco's shares down $1.03 per share, more than 22%, to close on March 31, 2009, at $3.52 per share, on unusually heavy volume. ¶125. On April 21, 2009, Caraco filed a report with the SEC further disclosing that "[o]n April 17, 2009, as a precautionary measure, Caraco … voluntarily initiated a recall of certain product lots manufactured in its Detroit, MI facility." ¶127.

The FDA again issued Caraco a Form FDA 483 on May 12, 2009, listing eighteen observations, including fundamental failures in operating procedures including a number of repeat observations from earlier inspections. ¶80. Yet on May 28, 2009, Caraco continued to downplay it problems in a press release that reassured investors that the Company had changed leadership in January 2009 and was taking steps to improve compliance. ¶129. In a filing with the SEC on June 15, 2009, Caraco claimed, among others, that "[w]e continue to gain effective support from Sun Pharma, in both quality systems and personnel, in the areas of quality and manufacturing," "[w]e remain extremely pro-active in regards to growing our business appropriately," and "[w]e remain confident that our implementation of corrective actions in compliance and quality will ultimately let us gain back our momentum of sales growth that we have enjoyed over the last several years." ¶131.

Finally, in the June 15, 2009 filing with the SEC, signed by defendant Movens and Shanghvi, Caraco nevertheless reassured investors "we believe we are substantially compliant with cGMP." ¶131.

F. The Day of Reckoning

On June 24, 2009, the United States Attorney for the Eastern District of Michigan filed a complaint for forfeiture of adulterated articles of drug (the "Forfeiture Complaint") on behalf of the United States directed at all articles of drug located at Caraco's Elijah McCoy, Farmington Hills or Wixom, Michigan facilities. ¶133. The Forfeiture Complaint alleged that the FDA had issued a Warning Letter to Caraco on October 31, 2008 identifying numerous significant GMP violations identified during a May 1-June 11, 2008 inspection but that Caraco, despite repeatedly representing it had corrected the deficiencies, was still in continuing and significant violation of cGMP as admitted in its June 19, 2009 letter to the FDA. *Id.*[11]

Finally, on June 25, 2009, investors learned the true extent of Caraco's severe and systemic manufacturing problems. ¶¶17,134-135. That day, the FDA announced that U.S. Marshals had seized drug products manufactured by Caraco from the Company's facilities. ¶134. According to the FDA, this action followed Caraco's continued failure to meet the FDA's cGMP requirements, which assure the quality of manufactured drugs. *Id.* The FDA stated that through the seizure, it sought to immediately stop the company from further

[11] These violations included, *inter alia*: (1) failure to follow written procedures for the storage and handling of components resulting in, for example, the placement and use of raw materials without proper documentation resulting in the loss of toxic digoxin drug substance; (2) failure to follow written procedures for the execution of the production and process control functions for "charge-in" of components resulting in, for instance, the use of the wrong components in batch processing of drugs; (3) failure to maintain accurate inventory records of components resulting in, for example, 27 inventory discrepancies that could not be reconciled; (4) failure to have written procedures for production and process control, resulting in, for example, the manufacture of tablet drug products before adequately evaluating processing issues; (5) the failure to establish and follow written procedures describing in-process controls or tests, resulting in, for instance, reliance on visual inspection to remove defective tablets even though the company's own investigations revealed that the visual culling process was not effective; (6) failure to use appropriate equipment, resulting in, for instance, the inability to assure consistent quality for Digoxin drug products; (7) failure to conduct thorough investigations of unexplained discrepancies in drug manufacture causing, for instance, the failure to timely investigate out of specification inventory reconciliation for nine different drugs and the failure to investigate the root cause of the discrepancies; (8) failure to establish and follow written procedures applicable to the quality control unit, resulting in, for instance, changes in material weighing and machinery that lead to subsequent problems in manufacturing; and (9) failure to conduct follow-up to investigations of complaints, resulting in, for example, the failure to evaluate the potential health hazard of thick or thin tablets as it regards under- or supra-potency. ¶133.

distributing drugs until there was assurance that the firm complied with good manufacturing requirements. *Id.*

On this news, shares of Caraco declined $1.79 per share, approximately 43%, to close on June 25, 2009, at $2.39 per share, on unusually heavy volume. ¶136.

V. PLAINTIFFS HAVE ADEQUATELY ALLEGED VIOLATIONS OF THE SECURITIES LAWS

A. Standard of Review

To survive a motion to dismiss, a plaintiff's request for relief need only be "plausible." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). In assessing the sufficiency of a complaint, courts "must construe the complaint in a light most favorable to the plaintiff, and accept all of [the] factual allegations as true." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 553 (6th Cir. 2001).[12] Additionally, "[w]hen an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." *Id.*

To state a claim for securities fraud under Section 10(b) of the Exchange Act, a plaintiff must allege: (1) "a material misrepresentation (or omission)"; (2) "scienter, *i.e.*, a wrongful state of mind"; (3) "a connection with the purchase or sale of a security"; (4) "reliance"; (5) "economic loss"; and (6) "loss causation, *i.e.*, a causal connection between the material misrepresentation and the loss." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005). Under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), which is applicable to Section 10(b) claims, "a plaintiff must now state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" which, in this circuit, is recklessness. *Helwig*, 251 F.3d at 548, 550. Defendants only challenge the sufficiency of the Complaint with respect to the first two elements; namely, falsity and scienter.

[12] Unless otherwise indicated, all internal quotations, citations, and emphasis are omitted.

B. Plaintiffs Sufficiently Allege That Defendants Made Materially False and Misleading Statements

Under the PSLRA, a plaintiff adequately pleads falsity by "specify[ing] each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. §78u-4(b)(1)(B). Plaintiffs satisfy this standard.

1. Plaintiffs Adequately Allege Defendants' False and Misleading Statements and the Reasons Why Such Statements Were False and Misleading

As the Sixth Circuit has declared, "a company may choose silence or speech elaborated by the factual basis as then known – but it may not choose half-truths." *Helwig*, 251 F.3d at 561; *City of Monroe Employees Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 673 (6th Cir. 2005); *see also Berson v. Applied Signal Technology, Inc.*, 527 F.3d 982, 987 (9th Cir. 2008) (holding that once defendants chose to speak regarding the Company's operations, "they were bound to do so in a manner that wouldn't mislead investors"); *In re K-Tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 898 (8th Cir. 2002) ("the law requires 'an actor to provide complete and non-misleading information with respect to the subjects on which he undertakes to speak'"); *Stransky v. Cummins Engine Co.*, 51 F.3d 1329, 1331 (7th Cir. 1995) ("If one speaks, he must speak the whole truth.").[13]

Elaborating upon this principle, SEC Rule 10b-5(b) prohibits "mak[ing] any untrue statement of a material fact or … *omit[ting] to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading*." 17 C.F.R. §240.10b-5 (emphasis added). "Under this provision, even though no duty to make a statement on a particular matter has arisen, once corporate officers undertake to make statements, they are obligated to speak truthfully and to make such additional disclosures as are necessary to avoid rendering the statements made misleading." *In re Par Phar., Inc. Sec. Litig.*, 733 F. Supp. 668, 675 (S.D.N.Y. 1990); *see also Virginia Bankshares,*

[13] Defendants contend that Caraco had no duty "to warn investors about an event that was not certain." Motion at 14. The Sixth Circuit has declared, however, that "matters that are not material because they are not so probable or relevant as to be required to be disclosed in a particular context may be material if information about them is stated falsely or misleadingly in communications that are not otherwise required to be made." *Helwig*, 251 F.3d at 555.

Inc. v. Sandberg, 501 U.S. 1083, 1098 n.7 (1991) (when a company chooses to speak, "there can be no question that the statement [it] d[o][es] make carrie[s] with it no option to deceive"). "A statement is misleading if a reasonable investor, in the exercise of due care, would have received a false impression from the statement." *In re Par*, 733 F. Supp. at 677.

Defendants argue that their statements are not false or misleading as a matter of law because they purportedly had no duty to disclose the risks posed by the warnings that the Company received from the FDA. Motion at 13-16. Defendants, however, misled the investing public by electing to speak about issues related to the Company's regulatory compliance but minimizing the significance of the FDA's warnings and Caraco's own noncompliance with FDA regulations. In fact, despite the Defendants' reassurances to the contrary, the FDA's warnings were significant not only because of the regulatory risk that they posed to Caraco, but also because of Caraco's shocking cGMP deficiencies that would have posed a substantial risk to the company even if they were not the subject of FDA 483 warnings. In fact, when the FDA eventually raided Caraco's facility and the full extent of its failures came to light, the effect upon Caraco was significant – and the effect on the company's shareholders was devastating.

Defendants made materially false and misleading statements in several areas, which the Complaint spells out in great detail.[14] For instance, Defendants made misleading

[14] As set forth throughout this section, Plaintiffs have more than adequately alleged that Defendants made misleading statements. In light of this, Defendants' attempt to elevate form over substance through 15 USC §78u-4(b)(1) fails utterly. Unlike the complaint in *In re The Goodyear Tire & Rubber Co. Sec. Litig.*, 436 F.Supp.2d 873 (N.D.Ohio 2006), the Complaint carefully sets forth the "reason or reasons why each statement was misleading." *Id.* at 904; *see* ¶¶101, 103, 105, 107, 109, 111, 113, 117, 119, 121, 123, 126, 128, 130, 132. The Complaint includes *far* more than "a long list of block quotes" lined up against "a conclusory list of omissions." *Havenick v. Network Exp., Inc.* 981 F.Supp. 480, 526 (E.D. Mich.1997). Rather, it includes carefully-selected statements, providing both context and particular emphasized text, and a thorough explanation for why each statement was misleading, thus "explain[ing] in what respect the statements at issue were false." *Pilarczyk v. Morrison Knudsen Corp.*, 965 F.Supp. 311, 321 (N.D.N.Y. 1997). Moreover, Defendants offer no support for their implied argument that 15 USC §78u-4(b)(1) requires that the identification of the misstatement, their explicit quotation, and the explanation of why it is wrong, must be contained within the same paragraph. Motion at 38. Thus, ¶123 is *not* the only paragraph to identify misleading sentences.

statements regarding employee training. The May 29, 2008 press release boasted of enhanced training, quoting Defendant Movens' assertion that, "Our training and succession planning is being enhanced to support our growth and predict future operational efficiencies. We are working with local universities and technical schools in order to provide the proper talented employees required to perform in a highly regulated business." ¶100. Defendants reiterated their boasts of a well-trained workforce in an October 2008 press release. ¶¶110-113. These statements naturally created the impression that Caraco was training its employees to properly grow the company in a "highly regulated business." However, Defendants knew, or were reckless in not knowing, several facts that contradicted their glib assertions.

As revealed in the FDA Form 483 following the inspection that occurred from May-June 2008, Caraco employees engaged in the manufacture and processing of a drug product actually lacked the training required to perform their assigned functions. ¶60. The letter indicated that cGMP training was not conducted by Caraco on a continuing basis and with sufficient frequency to assure that employees remained familiar with cGMP requirements applicable to them. *Id.* As an example, the Form 483 indicated that "review of training records of four employees in the Dispensing Department show incomplete documentation of minimum training requirements to enable a person to perform the assigned functions." ¶101. The employee training was so deficient, in fact, that CW1, a manufacturing manager at Caraco, reported that Caraco's poor infrastructure rendered it virtually incapable of properly training its employees to use the "ERP" system to track raw materials. ¶¶90(b), 101.[15] According to CW1, the ERP system was so difficult to use that it was nearly impossible to train employees to use it properly. *Id.* In fact, despite having a BS degree in Chemistry, CW1 admitted that it was hard for him/her to figure out the ERP system. *Id.* Caraco's inadequately trained employees thus were unable to use the ERP system to fully record movements of raw materials as they occurred in the dispensing area. *Id.* Senior employees were then forced to

[15] "ERP" was a material resource planning, or "MRP" system that was internally cobbled together by Sun Pharma.

make these entries into the system *after* they happened based on logs that operators were supposed to complete. ¶¶90(b), 101. Thus, contrary to defendants' false and misleading statements that improved productivity and increased cGMP compliance would result because of the hiring and retention of experienced staff and talented personnel, the FDA determined that Caraco employees lacked the basic training necessary for them to adequately perform their assigned functions.

Defendants also made misleading statements regarding the January 2008 recall. The June 10, 2008, Form 10-K for the 2008 fiscal fourth quarter and full year, signed by Defendants Movens and Shanghvi, minimized the then-recent recall. It claimed that "The product recall announced by the FDA was limited to a single compression machine malfunction, and affected two lots…. *The Company has responded accordingly and we believe we remain substantially compliant.* … We continue to focus on improving the amount of support in both quality assurance and quality control in order to continually improve our performance in quality.… We have focused our attention for continual improvement of our Corrective And Preventative Actions and cGMP, while adding the appropriate level of personnel to support our growth during Fiscal 2008…. We remain extremely pro-active in regards to growing our business appropriately." ¶102 (emphasis added). Defendants made similar assertions in a July 25, 2008 press release and Form 10-Q, ¶¶105-106. Then, in September 2008, merely weeks before the FDA issued its Warning Letter to Caraco, Defendant Shanghvi touted Caraco's business and regulatory compliance in an article in the *Business Standard*. ¶108.

The January 2008 recall had been as a result of customer complaints about "over and undersized pills." Defendants identified the reason for the recall as limited to a "particular machine." However, the over and undersized pills were actually part of a continuous problem with tablet variation before and during the Class Period and were not limited to one particular machine. According to CW4, CW5, CW6, CW7, CW8, and CW9, the Company had a rampant and pervasive problem producing tablets that were too thick or too thin. ¶103(a).

CW9 reported that, throughout his/her employment from March 2007 until June 2008, quality inspectors frequently discovered tablets that were too thick or thin, as well as tablets that were broken and/or chipped. ¶97(a). Likewise, CW8 corroborated this account and indicated that rampant problems with tablets being too thick or too thin were common knowledge within the Company. ¶96(a). Moreover, CW6 noted that the Sejong machines being used for large production were causing problems because these machines were designed to be used for making small lots of vitamins, not large quantities of pharmaceutical grade drug products. ¶94(b). CW4 and CW5 also indicated that the "Sejong" tablet press machines Caraco was using were not proper for producing a pharmaceutical grade product. ¶93(c). CW5 indicated that the Company needed better compression machines in order to reduce tablet production problems, including the thick/thin problems. *Id.*; *see also* ¶ 103(a). In fact, the Company received numerous complaints from customers during the Class Period about pills manufactured by the Company that were either over or undersized. ¶¶168-69.

Then, on March 31, 2009, Caraco announced a "voluntary" Digoxin recall. ¶82. However, Defendants failed to disclose that the cGMP problems went well beyond this single product. ¶126. Just weeks later, on April 17, 2009, Caraco initiated a recall of certain products because "some of the tablets being oversized or undersized." ¶84. Although the Company claimed that the recall was voluntary, it was actually initiated by the FDA. ¶128. According to FDA documentation the products were manufactured from "3/30/2008 to 12/08/2008" and were distributed from "04/24/2008 to 01/28/2009." The products listed in the FDA recall documents were limited to 2,138 bottles containing 1,000 tablets of "Clonazepam Tablets, USP, 0.5 mg," 80,055 bottles containing 1,000 tablets of "Metoprolol Tartrate Tablets, USP, 25 mg," and 4,330 bottles containing 1000 tablets of "Metoprolol Tartrate Tablets, USP, 50 mg." ¶84. Caraco and Defendant Movens later admitted that the Company was having "reoccurring variability product issues." ¶88. Thus, in the Company's June 19, 2009 letter to the FDA, the Company had established a "variability study" in November 2008 to address the issue, and conceded that the most significant reoccurring

variability issues were occurring with the Company's Metoprolol, Clonazepam, Digoxin, and Metformin products. *Id.*; *see also* ¶103(a).

The problem with the Company's "reoccurring variability product issues" were so severe that later in the Class Period, as admitted by Defendant Movens and Caraco in a February 19, 2009, letter to the FDA, "We have stopped most of our internal research and development activities to allow the R&D team to act as additional support for tech services. They are analyzing the trends for recurring product anomalies and are taking appropriate action as necessary to eliminate any remaining issues with product quality." ¶79. The subsequent seizure of ***all*** of Caraco's manufactured drug products and ingredients was the result of these ongoing and pervasive manufacturing and compliance issues – issues that defendants falsely and misleadingly minimized in the Company's public statements. ¶103(a).

Defendants also made misleading statements that Caraco was "substantially compliant" with FDA requirements. Contrary to the Company's assertions, Caraco had not "responded accordingly" to the Form 483s, and was not "substantially compliant" with cGMP requirements. Defendants lacked any reasonable basis to state a belief that Caraco was "substantially compliant," for several reasons.

The FDA Form 483 issued the very day after the June 10, 2008 statements listed at least 14 significant observations evidencing failures in fundamental operating procedures regarding the manufacture of drugs for human consumption. ¶60. These observations included: a lack of written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess; failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed (such as the failure to fully investigate incidents of contaminated, adulterated or out-of-specification drugs or raw materials); written production and process control procedures not documented at the time of performance; and cGMP training not conducted on a continuing basis and with sufficient frequency to assure that

employees remain familiar with cGMP requirements applicable to them; and procedures for the cleaning and maintenance of equipment deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance. *Id*.; *see also* ¶103(b).

Witnesses were aware of these existing problems that demonstrated that Caraco was not substantially compliant with FDA regulations. CW5 stated that he/she was hired by Caraco to "fix everything." For example, the standard operating procedures, or "SOPs," were in disarray. Upon his/her arrival at Caraco in July 2008, CW5 immediately faced *over 1,000 SOPs* that needed to be updated, and in some cases, *the SOPs had not been updated in 12 to 14 years*. ¶93(l). CW2 indicated that there was an utter lack of proper manufacturing practices and quality assurance at Caraco. ¶91(a). For example, CW2 noted that the SOPs were changed every day. *Id.* Similarly, according to CW2, adverse drug experience, or "ADE," reports were consistently delayed. ¶91(e). Complaints would come in through customer service from a pharmacy or a customer, concerning issues such as insufficient pills in the bottle, broken pills, or a bad reaction to the drug. However, complaints were written up and sent to Quality Assurance; Quality Assurance would review the problem with the originating department and, after a delay in which Caraco management would protect themselves, Caraco would finally file a report with the FDA. *Id.* According to CW1, ADE reports were filed with the FDA belatedly, as the two employees who filed the reports were occupied by their customer service duties, taking phone calls and emails from customers, pharmacies, and distributors. ¶90(d). "[A]llegations of specific problems undermining a defendant's optimistic claims suffice to explain how the claims are false." *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005).

CW4 also confirmed the rampant manufacturing problems at Caraco. ¶¶93(a)-(l). He/she stated that in 2008 alone, there were over 1,000 incidents of problems, including weight variation, contaminants such as hair found in the product, or tablets that were too

thick/thin. *Id.* Indeed, CW4 stated that he/she had seen more hair contamination problems in a week than he/she had seen in all of his/her combined 40 years in manufacturing. *Id.* CW5 also confirmed that there were serious, rampant problems with tablet variation. *Id.* CW5 noted that tablet variation was a serious problem, as Digoxin, for example, was a Class 2 drug that could be lethal at the wrong dosage. *Id.* CW5 noted that in one set of tests weighing over 900,000 tablets, approximately 2% were found to be of the wrong size – an incredibly high ratio of defective product for pharmaceuticals. *Id.* Indeed, when CW5 first arrived, Caraco was "like the wild west." *Id.* CW5 also described CEO Movens's intimate knowledge of the rampant problems at Caraco. *Id.* CW5 attended meetings to discuss the manufacturing problems at the Company. *Id.* Defendant Movens was directly involved with, and keenly aware of, the quality issues at the Company that demonstrated the falsity of the Company's public statements. Additionally, according to CW10, between 2006 and 2008, quality review board meetings and operations meetings were held. ¶98(b). CW10 stated that Defendant Movens instructed all senior management and managers in general in operations and quality that any issues regarding quality should be directed to him first. *Id.* As a result, CW10 indicated that in some cases, Daniel Barone, the Director of Quality, would learn about quality issues only after Defendant Movens. *Id.*

Other allegations further demonstrate the falsity of defendants' statements. CW3 indicated that Caraco had "many infractions." ¶92 For example, according to CW3, an employee would blend the ingredients, then test the mixture to make sure it was correct; but production would consistently start making tablets *before* the tests were complete. If a problem was found later, the machine operators were blamed. *Id.*; *see also* ¶103(c). Indeed, as soon as CW6 started at Caraco, he/she saw things that were "totally wrong." ¶94(a). CW6 was concerned about the quality of the product and noted that the set up in the compression stage of manufacturing was incorrect, resulting in metal shavings getting into the product. He/she tried to rectify the problem with management but the ethic was "more about pushing production than quality." *Id.* According to CW6, every time there was an issue, management

wanted to bypass the issue so that they could maximize production. *Id.*; *see also* ¶103(c). CW4 and CW5 similarly recounted the Defendants entire focus was on growing production at the expense of compliance. CW4 stated that even if a product did not meet the in-house specifications, the manufacturing people would release it anyway. ¶93(d). According to CW4, the problem stemmed from the attitude of management to "get the tablets out the door." Machines were not allowed to be shut down even when updating SOPs. *Id.* CW5 corroborated this account, stating that Kaushik Gandhi ordered continued production without interruption – even during SOP revisions. *Id.*; *see also* ¶ 103(c). Despite Defendants' boasts that the Company brought aboard new production leadership to ensure substantial cGMP compliance, the new personnel, Ajmera and Mehta, were if anything ***more*** willing to sacrifice compliance for production. ¶¶122-23.[16] Defendants continued to minimize the extent of their non-compliance even as the truth began to emerge. ¶¶130, 132. Thus, Caraco failed to remedy deficiencies identified by the FDA in previous observations, demonstrating that the Company was not substantially compliant with FDA requirements as defendants falsely and misleadingly represented. ¶¶103(b), 113, 117, 119, 121, 126, 130, 132.

2. Defendants' Statements Were Material and the Court Cannot Decide Materiality As a Matter of Law at the Pleading Stage

Defendants do not dispute that they made the misrepresentations alleged in the Complaint. Instead, they argue that they should be immune from responsibility for their misstatements because they were not "material" – in other words, "there [is not] a substantial likelihood that the disclosure of the omitted fact[s] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). However, such an argument is inappropriate for a motion to dismiss. At the motion to dismiss stage, omissions are material unless the omitted information was so "obviously unimportant to a reasonable investor that

[16] Thus, contrary to Defendants' response to ¶¶122-123, Motion at 39, as those paragraphs explain, although new leadership had been installed, Defendants knew, or were reckless in not knowing, that the new leadership was not intended to effect the purported goals.

reasonable minds could not differ on the question of their unimportance." *Bridgestone*, 399 F.3d at 681. Thus, "[d]etermining materially in securities fraud cases should ordinarily be left to the trier of fact." *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1178 (9th Cir. 2009); *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32, 240 (1988); *TSC*, 426 U.S. at 450.

Although Plaintiffs are not required to establish materiality at this stage, *Basic*, 485 U.S. at 231-32, the misrepresentations alleged are clearly material. Defendants induced investors to provide the money for an operation that depended upon regulatory compliance; reassured the investors that whatever regulatory issues it had were minor and controllable; and meanwhile ran the operation with minimal-if-any regard for compliance. *See, e.g.*, ¶¶7, 89-98. Courts have found similar statements to be material. *See McGuire v. Dendreon Corp.*, No. C07-800MJP, 2008 WL 5130042 at *5, *6 n.4 (W.D. Wash. Dec. 5, 2008) (contents of Form 483 are material, and defendant's statement that "we hosted a good [FDA] inspection, I think" is actionable); *In re Zenith Lab. Sec. Litig.*, Civ. No. 86-3241A, 1993 WL 260683 at *2-*4,*8-*9 (D. N.J. Feb. 11, 1993) (denying summary judgment where generic drug manufacturer's officers projected optimism to investors in face of negative Form 483s). In fact, the importance of FDA action is amplified where, as here, the corporate strategy depends on attaining the market advantage of winning the initial ANDA approval. *See* ¶ 42; *see also Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1129-30 (C.D. Cal 2005) ("The facts related to the issuance of the Form 483 and the problems described therein were 'material'… *[a]ny* facts bearing on possible delays in FDA approval" are material when corporate strategy depends on timely approvals) (emphasis added). For instance, in *In re Able Lab. Sec. Litig.*, Civ. Action No. 05-2681 (JAG), 2008 WL 1967509 (D.N.J. Mar. 24, 2008), a case with factual allegations virtually identical to those here, the court characterized the following facts as material in denying defendants' motion to dismiss:

> ***The Complaint alleges several instances in which Defendants provided material misstatements or omissions in violation of the Securities Exchange Act of 1934.*** On March 20, 2002, ***Able "'hired individuals who were knowledgeable and committed to [the FDA's current Good Manufacturing Practices ("cGMP")] compliance, and instituted operational procedures that enforce cGMP compliance***.'". . . On March 25, 2003, Able filed SEC Form

> 10-K, which contained their annual report for 2002 and "***represented that Able was in compliance with all FDA manufacturing regulations***." On March 15, 2004, Able filed SEC Form 10-K, containing its annual report for 2003, which stated "'***we believe we are currently in compliance with all applicable FDA requirements***' and '[w]e do not expect the [Generic Drug Enforcement Act of 1992] to have a material impact on the review or approval of our AND As.'" . . . On May 7, 2004, Able filed SEC Form 10-Q. . . .This Form also disclosed that the FDA had initiated an inspection of the South Plainfield Facility in January of 2004 and had issued a warning letter to [CEO] Wadekar. Regarding the warning letter, Able said, in the Form 10-Q, "'***we believe that the warning letter may not materially affect our operations***.'". . . The Company further stated ***"'[w]e expect to be able to address the FDA's observations in a timely and effective manner, and we believe the warning letter may not materially affect our operations***.'" . . . . On April 5, 2005, Able initiated a nationwide recall of approximately 29,000 packages of an anti-nausea medication due to "impurity failures." Able also initiated a Florida and Ohio recall of 3,034 packages of a beta blocker due to instability. . . . . Defendant Wadekar responded that the impact "was fairly contained and the recall" would have no impact on the second quarter. . . .On May 10, 2005, Able filed SEC Form 10-Q which stated . . .[***W]e have initiated a thorough internal evaluation of our operating practices with the knowledge of the FDA***. . . . ***We have also retained the services of a highly reputable outside consulting firm to assist us in this initiative.***'"

Id. at *3-*8. Thus, false claims that a "Company believes it is in material compliance with cGMP standards" are actionable under Section 10(b) and Rule 10b-5. *See In re Copley Pharm., Inc.Sec. Litig.*, Civ. A. No. 94-11897-WGY, 1995 WL 169215 (D. Mass. Mar. 16, 1995).[17]

Defendants also claim that they are immune from liability because, they argue, their misrepresentations constituted "soft information," such as opinions or predictions, for which

[17] The cases Defendants cite are distinguishable. *Robbins v. Moore Med. Corp.*, 894 F.Supp. 661 (S.D.N.Y. 1995), a summary disposition opinion, involved "routine" inspections by the FDA, and, unlike here, defendant reasonably believed itself to be in material compliance. *Id.* at 674; *see also In re Indep. Energy Holdings PLC Sec. Litig.*, 154 F. Supp. 2d 741, 760 (S.D.N.Y. 2001) (overruled on other grounds) (distinguishing *Robbins* and finding that "[w]hile… securities laws may not require disclosure of possible future sanctions, they certainly require disclosure of information that would permit an investor to appreciate the risk that the future sanction may arise."). *In re Discovery Lab. Sec. Litig.*, No. 06-1820, 2006 WL 3227767 (E.D. Pa. Nov. 1, 2006), concerned statements about *a different company's product* in a different time period; the Court strongly implied that it would find misstatements about a company's own production, such as here, to be material. *Id.* at *11 ("categorical difference in materiality to … investors between problems in the manufacture of [company]'s flagship product and problems in the manufacture of *another* company's product in the same facility *seven years earlier*.") (emphasis in original). Finally, in *Public Pension Fund Group v. KV Pharm. Co.*, No. 4:08-CV-1859 (CEJ), 2010 WL 681443 (E.D. Mo. Feb. 22, 2010), the complaint alleged the findings of the Form 483s, but, unlike here, did not provide independent corroboration that the company actually violated cGMPs. *Id.* at *10.

they cannot be held responsible. Motion at 14-16. This contention is also incorrect. As the Sixth Circuit has declared, "the protections for soft information end where speech begins." *Helwig*, 251 F.3d at 560. As the court in *Helwig* explained:

> If – as defendants contend – the protection for soft information remains intact even after a company speaks on an emerging issue, the speaker could choose which contingencies to expose and which to conceal. On any subject falling short of reasonable certainty, then, a company could offer a patchwork of honesty and omission. This proposition is untenable, however, both as a matter of policy and precedent.

Id. at 560-61; *see also ACA Financial Guaranty Corp. v. Advest, Inc.*, 512 F.3d 46, 62 n.11 (1st Cir. 2008) ("Depending on circumstances, some statements of opinions or estimates may qualify as false or misleading statements of fact."). Thus, "opinions may be deemed false or misleading under the securities laws." *Bridgestone*, 399 F.3d at 670, 674 (an "opinion or puffery ... in particular contexts when it is both *factual and material* ... *may* be actionable) (emphasis in original); *see also McGuire*, 2008 WL 5130042 at *5.

Defendants' statements are actionable because they were based upon, and an integral part of, verifiable factual statements that were material to investors. The "opinion" concerned compliance with objective criteria such as the cGMP regulations. *See Bridgestone*, 399 F.3d at 672 (claim that conclusion is supported by "objective data" can be misrepresentation); *Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989) ("What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation."); *In re Washington Mut., Inc. Sec., Derivative & ERISA Litig.*, 2009 WL 3517630, at *22 (W.D. Wash. Oct. 27, 2009) (holding that a statement of opinion is actionable when it is based upon a material, verifiable statement of fact). Whether or not the Company was, in fact, compliant with cGMP regulations was an issue that was subject to objective verification. Thus, Defendants' so called "opinions" that the company was in substantial compliance with cGMP regulations could not have been offered in good faith, as they were aware of (or reckless for not being aware of) the pervasive problems undermining

their false and misleading statements. Defendants' argument, moreover, raises an issue of fact that is inappropriate for resolution at the pleading stage. *See In re ProQuest Sec. Litig.*, 527 F. Supp. 2d 728, 744 (holding that arguments that statements are puffery "really go to challenging the substance of the statements" and that complaints are "not subject to dismissal on these grounds"); *Harvey M. Jasper Ret. Trust v. Ivax Corp.*, 920 F. Supp. 1260, 1268 (S.D. Fla. 1995) ("Defendants' assertion that its [sic] statements were mere puffing raises an issue of fact.").

Defendants did not merely fail to foresee the FDA's future actions. Rather, they knew, or were reckless in not, knowing that the FDA's warnings were correct, and that their facility was plagued by pervasive cGMP problems, and they spoke about such warnings without fully disclosing such risks.[18] *See, e.g.*, ¶7. Moreover, Defendants were required to "permit an investor to appreciate the risk" of such sanctions. *In re Indep. Energy Holdings*, 154 F. Supp. 2d at 760. By minimizing the risks posed by the cGMP problems, Defendants deprived investors of the ability to assess such information in making their investment decisions and significantly altered the "total mix" of information available. *Basic*, 485 U.S. at 231-32.[19]

Defendants' assertion that they are immune from liability because the FDA Form 483s were publicly available (Motion at 10-13) is without merit. Defendants are attempting to invoke a truth-on-the-market defense, but courts have routinely declared that "[t]he truth-on-the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a §10(b) complaint for failure to plead materiality." *Ganino v. Citizens Utils. Co.*, 228 F.3d

[18] Therefore, *Anderson v. Abbot Labs.*, 140 F. Supp. 2d 894 (N.D. Ill. 2001) is distinguishable; in *Anderson*, the Court relied on the fact that "Plaintiffs have not alleged any facts suggesting that defendants did not have a good faith basis for disputing the allegations." *Id.* at 907. Here, Plaintiffs have alleged actual cGMP problems so severe and pervasive that Defendants had no good faith basis upon which to dispute the FDA's assessment. *See, e.g.*, ¶¶7, 101, 103.

[19] This is not a case such as *In re Sofamor Danek Group, Inc.*, 123 F.3d 394 (6th Cir. 1997), where the FDA ultimately did not initiate action against the company. *Id.* at 402. Here, the substantial risk that the Defendants hid from investors materialized. Moreover, unlike in *In re Guidant Corp. Sec. Litig.*, 536 F. Supp. 2d 913 (S.D. Ind. 2008), the Defendants did not fail to adequately describe the nature of a product defect; rather, they essentially engaged in a cover up of their known (or recklessly unknown) cGMP violations by downplaying FDA assessments that they knew or should have known to be, if anything, not alarming enough.

154, 167 (2d Cir. 2000); *see also Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 735 (7th Cir. 2004) ("A 'truth-on-the-market' defense is available in principle ... but not at the pleading stage.").[20] Moreover, the Form 483s only revealed a small part of the problems known to Defendants. The true nature of the pervasive cGMP problems and defendants' unwillingness to adequately confront them were not revealed until the end of the Class Period. If the undisclosed information was truly digested by the market, then Caraco's stock price would have reflected the incorporation of such information. The fact that the Company's stock price dropped 42.82% when Caraco disclosed adverse information on June 25, 2009 is indicative the market was not aware of the full extent of the negative information. ¶¶135-36, 157; *Bridgestone*, 399 F.3d at 675-76. "At the motion-to-dismiss phrase, the Court declines to find that the allegedly concealed information was already disclosed to the market 'with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by insider's one-sided representations.'" *In re Dura Pharms., Inc. Sec. Litig.*, 548 F. Supp. 2d 1126, 1144 n.15 (S.D. Cal. 2008). Thus, plaintiffs have adequately alleged falsity.[21]

Even where public information is available, the information provided by a company itself is especially significant. *Ballan v. Upjohn Co.*, 814 F. Supp. 1375, 1382 (W.D. Mich. 1992) (citing *TSC Industries*, 426 US at 449). While the Form 483s may have been publicly-available, they only "scratched the surface" of the true nature of Caraco's "wild west"

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[20] *See Immune*, 375 F. Supp. 2d at 1036-37 ("the Court cannot conclude as a matter of law that the market had sufficient credible information indicating that Defendants' optimism about REMUNE was unwarranted"); *In re Lockheed Martin Corp. Sec. Litig.*, 272 F. Supp. 2d 928, 938 n.11 (C.D. Cal. 2002) ("'The truth on the market defense presented by the defendants necessarily involves a fact-intensive inquiry which is ill-suited to a motion to dismiss.'").

[21] Defendants also contend, without citing any authority, that a claim for securities fraud cannot be based upon statements that are literally true. Motion at 39. However, "[s]ome statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1034 (C.D. Cal. 2008); *Immune*, 375 F. Supp. 2d at 1021. "Courts have long held that general disclaimers of accuracy do not shield sellers who knowingly make false statements." *In re Nat.'l Century Fin. Enterprises, Inc. Inv. Litig.*, 541 F. Supp. 2d 986, 1005 (S.D. Ohio 2007).

operation. ¶7. Unlike in *Sofamor Danek*, the investors could *not* independently appraise the FDA's assessment, because Defendants had hidden the true nature and extent of the violations. *Sofamor Danek*, 123 F.3d. at 402 ("any analyst could easily obtain a copy of the letter and could make an independent judgment of its significance").

C. The PSLRA's Safe Harbor Provision Does Not Protect Defendants' False and Misleading Statements

Defendants also contend that their false and misleading statements are protected by the PSLRA's safe harbor provision. Motion at 40-41. Defendants' argument fails for several reasons. First, most of the statements alleged are statements of historical or present fact that are not entitled to protection. The PSLRA's safe harbor provision only applies to statements "identified" as "forward-looking" and "accompanied by meaningful cautionary" language "identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. §78u-5(c)(1)(A). Accordingly, the safe harbor provision and its bespeaks caution antecedent do not apply to defendants' statements of current or historical fact. *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 705 (7th Cir. 2008) ("*Tellabs II*"). The "misrepresentation of present or historical facts cannot be cured by cautionary language." *P. Stolz Family P'ship L.P. v. Daum*, 355 F.3d 92, 96-97 (2d Cir. 2004). Moreover, "a mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present." *Tellabs II*, 513 F.3d at 705; *see also In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 213 (1st Cir. 2005) ("The mere fact that a statement contains some reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the statement.").

Contrary to defendants' assertion that all the alleged statements were forward-looking (Motion at 40-41), many of defendants' statements were assertions of historical or current facts to which the safe harbor provision does not apply. For example, defendants represented: "[o]ur training and succession planning ***is being enhanced*** to support our growth and predict future operational efficiencies" (¶100); "[w]e ***are working*** with local universities and

technical schools in order to provide the proper talented employees required to perform in a highly regulated business (¶100); "[t]he product recall announced by the FDA ***was limited*** to a single compression machine malfunction, and ***affected*** two lots (¶102); "[w]e ***have focused*** our attention for continual improvement of our Corrective And Preventative Actions and cGMP, while ***adding*** the appropriate level of personnel to support our growth during Fiscal 2008 (¶102); "[s]ignificant resources ***have also been spent*** to improve overall lab operations (¶106); "[o]ur manufacturing personnel ***are*** going through more rigorous training at the time of hire, and thereafter, in order to maintain our compliance and quality (¶106); "[t]he Company ***had responded*** to all the observations made in the Form 483 within thirty days thereof, and corrective actions ***were taken and substantially completed*** (¶114); "Caraco believes it ***has addressed*** the concerns in the warning letter appropriately (¶118); "[w]e ***have*** corrective actions in place and ***continue*** to work to improve our quality system (¶120); "[i]n January 2009 we ***changed*** our leadership in both manufacturing and quality control in order to better align these areas with our corporate goals and ***have taken*** other steps to improve cGMP compliance and quality system (¶129); and "[t]he personnel that we ***have added have improved*** the competency level which should improve the performance of our manufacturing and quality areas (¶131) (emphasis added). Because these are statements of present or historical fact, they are not forward-looking and are not protected by the safe harbor provision.

Second, defendants' disclaimers do not constitute meaningful cautionary language. As the Sixth Circuit has recognized, "boilerplate warnings will not suffice ... [t]he cautionary statements must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements, such as, for example, information about the issuer's business." *Helwig*, 251 F.3d at 558-59; *see also Lormand v. US Unwired, Inc.*, 565 F.3d 228, 244-45 (5th Cir. 2009); *Asher* 377 F.3d at 732. In their Motion, defendants only point to the following language which they claim constitutes meaningful cautionary language: (1) the forward-looking statements "are not guarantees of

future performance and are subject to risks and uncertainties that cannot be predicted or quantified;" (2) the Company will "continue to focus and improve on FDA compliance" and will "increase cGMP training to accommodate growing staff and compliance;" and (3) one risk or uncertainty of investing with Caraco was the "lack of success in attaining full compliance with regard to regulatory and cGMP comlplaince." Motion at 41. Each of these statements, however, fails to constitute meaningfully cautionary language. The first statement is classic boilerplate because such changes constitute "factors that are so broad that they apply to any business that sells products to consumers" and therefore does not convey substantive information about the Company. *Yanek*, 388 F. Supp. 2d at 1123; *Helwig*, 251 F.3d at 558-59; *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 708-10 (3d Cir. 1996). The second statement is actually not a warning at all; the statement does not inform investors of any factors that could cause actual results to differ materially from those in the forward-looking statements. *Lormand*, 565 F.3d at 244-45. The final statement also too vague to be meaningful because it fails to fully apprise investors of the risks associated with the Company's failure to attain regulatory compliance. *Lormand*, 565 F.3d at 244-48; *Asher*, 377 F.3d at 732.

Third, defendants' disclaimers were also inadequate because the risks posed by Caraco's failure to comply with manufacturing regulations had already materialized and were greater in magnitude than represented. "To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit." *Huddleston v. Herman & MacLean*, 640 F.2d 534, 544 (5th Cir. 1981), *aff'd*, 459 U.S. 375 (1983); *Lormand*, 565 F.3d at 246-48; *Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004). As discussed herein, defendants were fully aware of manufacturing problems at the Company that demonstrated that the risks of non-compliance had already materialized. "Cautionary language can never be 'meaningful' if it warns of risks that have already materialized." *In re 21st Century Holding Co. Sec. Litig.*, No. 07-61057-CIV, 2008 WL 5749572, at *13 (S.D. Fla. Nov. 7, 2008); *In re Nash Finch Co.*, 502 F. Supp. 2d 861, 873 (D. Minn. 2007).

Fourth, with respect to defendants' forward-looking statements, defendants had actual knowledge of the falsity of such statements. The safe harbor provision is inapplicable where, as demonstrated herein, a plaintiff adequately alleges that defendants actually knew that their statements were false and misleading. 15 U.S.C. §78u-5(c)(1)(B); *Tellabs II*, 513 F.3d at 705. Finally, dismissal on the pleadings under the safe harbor defense "requires a stringent showing" by defendants. *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 947 (9th Cir. 2005). "There must be sufficient 'cautionary language or risk disclosure [such] that reasonable minds could not disagree that the challenged statements were not misleading.'" *Id.* at 947; *Lormand*, 565 F.3d at 248; *Westinghouse*, 90 F.3d at 708-10; *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1214 (1st Cir. 1996). Courts generally cannot determine meaningfulness at the pleading stage because "any issuer could list its lines of business, say 'we could have problems in any of these,' and avoid liability for statements implying that no such problems were on the horizon even if a precipice was in sight." *Asher*, 377 F.3d at 733. Here, application of the PSLRA's safe harbor provision "is not so obvious as to be decided as a matter of law." *EP MedSystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 877 (3d Cir. 2000).

D. Plaintiffs Allege Strong Evidence of Defendants' Knowledge and Recklessness

For purposes of a securities fraud claim, "scienter" means the intent to deceive, manipulate, or defraud. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). Importantly, "courts must consider the complaint in its entirety.... The inquiry... is whether ***all*** of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23 (emphasis in original). A strong inference of scienter arises if, "[w]hen the allegations are accepted as true and taken collectively," a reasonable person would "deem the inference of scienter at least as strong as any opposing inference[.]" *Id.* at 325; *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 683 (6th Cir. 2004).

In the Sixth Circuit, courts recognize that defendants' recklessness satisfies the scienter requirement. *Helwig*, 251 F.3d at 550. Additionally, the Sixth Circuit recently affirmed the "at least as compelling" standard set forth in *Tellabs* in *Frank v. Dana Corp.*, 547 F.3d 564 (6th Cir. 2008). "[T]he Supreme Court expressly held that a complaint will survive a motion to dismiss so long as 'a reasonable person would deem the inference of scienter cogent and ***at least as compelling*** as any opposing inference one could draw from the facts alleged'" *Id.* at 571 (citation omitted, emphasis in original). In doing so, the Sixth Circuit instructed Courts in this Circuit to:

> conduct a 'comparative inquiry' and assess the possible competing inferences that could be drawn from the allegations, including 'plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff.'

Id. (citation omitted). The Sixth Circuit directed that in conducting this "comparative inquiry" the inference be ***drawn in favor of plaintiffs***. *Id.*; *Tellabs*, 551 U.S. at 324.

In considering whether plaintiffs' complaint, ***as a whole***, raises an inference of scienter, the Sixth Circuit has set forth some non-exhaustive guideposts to consider in evaluating scienter. *Helwig*, 251 F.3d at 552 ("cases will allege different facts with possibly different results"). The *Helwig* factors include: (1) insider trading; (2) divergence between internal reports and external statements; (3) proximity of fraudulent statements and later disclosure of inconsistent information; (4) bribery; (5) existence of an ancillary lawsuit charging fraud and quick settlement of that lawsuit; (6) disregard of the most current factual information before making statements; (7) disclosure of accounting information in such a way that its negative implications could only be understood by someone with a high degree of sophistication; (8) the personal interest of certain directors in not informing disinterested directors of an impending sale of stock; and (9) the self interested motivation of defendants in the form of saving their salaries or jobs. *Helwig*, 251 F.3d at 552; *In re Huffy Corp. Sec. Litig.*, 577 F. Supp. 2d at 968. Allegations comporting with any of these nine factors – or

with other factors not enumerated relevant to the particular facts of the case – contribute to a strong inference of scienter.[22]

1. The Divergence Between Negative Internal Reporting and Defendants' Positive Statements to the Market and Defendants' Disregard of the Most Current Factual Information Before Making Statements Support a Strong Inference of Scienter

Two of the "fixed constellations of facts" probative of fraud are the "divergence between negative internal reporting and defendants' positive statements to the market" and defendants' "disregard of the most current factual information" while making such statements. *Helwig*, 251 F.3d at 552; *Bridgestone*, 399 F.3d at 683. Here, defendants consistently had the most current information about Caraco before making statements and there was a divergence between defendants' internal reports and their external statements on particular subjects. Defendant Daniel Movens had intimate knowledge of the rampant problems at the Company through twice daily reports involving the rampant quality defects. ¶91(e), ¶103(b)(iv). Additionally, between 2006 and 2008 there were two separate meetings involving the quality review board and operations meetings. ¶103(b)(v). Defendant Movens gave instructions to all senior management and managers that any issues involving quality should be directed to Movens first. ¶103(b)(v). Together, the reports alerted defendants and other Caraco executives that there were severe problems with the quality of the pharmaceuticals produced by Caraco. ¶160-69. This information contrasted with the Company's public statements that the production issues were isolated incidents, not material and that the Company was substantially compliant with FDA rules. ¶¶54, 101-03, 106, 112-13, 120-21, 160. Additionally, though Defendant Movens stated that Caraco was training its employees to properly grow the Company in a highly regulated business, he received reports that employees did not even have the minimum training requirements necessary for the job. ¶¶100(a), 163-

[22] The *Helwig* court acknowledged that "[b]ecause Congress did not endorse or prohibit a particular manner of pleading, we cannot disregard any set of facts as insufficient as a matter of law." *Id.* at 551-52. Indeed, a plaintiff does not need to plead facts for each factor to properly plead scienter. *Bridgestone*, 399 F.3d at 687 (adequate scienter allegations despite finding that four of the nine *Helwig* factors "admittedly are not probative of scienter").

64. Courts, moreover, have held that defendants' receipt of Form 483s and FDA warning letters and their public statements contradicting the information contained in such notices can support a finding of recklessness:

> The Form 483 and the warning letter provided notice to the defendants that serious problems existed in the manufacturing process at Able, and even informed the defendants that they were responsible for following upon on, and further investigating, the problems. ***Failing to investigate the FDA warning is an "extreme departure from the standards of ordinary care" and demonstrates that the defendants were reckless for not knowing their statements about Abie's [sic] compliance with FDA standards and other quality control issues were false***.

Able, 2008 WL 1967509, at *16.

Defendants claim that because Caraco purportedly had no duty to "warn investors about an event that was not certain," that "Caraco could not predict the future" and did not know "that the FDA was going to initiate a seizure action" plaintiffs cannot state a claim. Motion at 13-16. Courts, however, have rejected this argument:

> Defendants claim that Plaintiffs must show Defendants "knew that the FDA would find STAAR's September 29, 2003 written response inadequate, knew that the FDA would ultimately issue a Warning Letter, and knew that the Warning Letter would state that the FDA would not approve any new STAAR devices until STAAR's 'quality system' deficiencies were corrected." ***However, Defendants attempt to raise the standard for scienter far beyond what is required by the PSLRA, ... [T]he PSLRA does not require that Plaintiffs show that Defendants were capable of predicting the future.***

Yanek, 388 F. Supp. 2d at 1130 (emphasis added). Thus, plaintiffs' allegations that defendants "received regular information" concerning "problems which they should have realized contradicted the company's public statements" give rise to a strong inference of scienter. *In re Cabletron Sys.*, 311 F.3d 11, 39 (1st Cir. 2002).[23]

[23] Defendants' demand for more specific details of the contents of the report is unrealistic at this stage of litigation as the physical reports remain in defendants' possession. *See, e.g.*, *Pirraglia v. Novell, Inc.*, 339 F.3d 1182, 1193 n.14 (10th Cir. 2003) (a requirement that plaintiffs allege the specifics of internal paperwork "is asking too much of the plaintiffs, who cannot be expected, at the pleading stage, to describe in detail documents and paperwork that would presumably be kept, if at all, in Novell's private files"); *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1990) ("Particularly in cases of corporate fraud, plaintiffs cannot be expected to have personal knowledge of the details of corporate internal affairs."). Such specific evidence – direct evidence – has not been required at the motion-to-dismiss stage. *Pirraglia*, 339 F.3d at 1193 n.14; *accord Cabletron Sys.*, 311 F.3d at 33

2. The Confidential Witnesses Add to the Strong Inference of Scienter Alleged

Numerous courts have recognized that statements from confidential witnesses can support a strong inference of scienter. *See, e.g., In re Daou Sys., Inc.*, 411 F.3d 1006, 1015-16 (9th Cir. 2005); *Tellabs II*, 513 F.3d at 712; *In re Cabletron Sys. Inc.*, 311 F.3d at 28-31; *In re Am. Serrv. Group, Inc.*, 2009 WL 1348163, at *58 (M.D.Tenn. March 31, 2009). Plaintiffs' allegations are corroborated by ten former employees – some of whom had hands-on responsibility for the reports' contents, or attended the periodic meetings alleged.[24] For example, CW 4 and CW 5 both communicated serious manufacturing problems to Movens directly. ¶¶93, 164. CW 5's complaint that it was impossible to meet the increased production demands was met with Movens' reply that his "hands were tied" due to SunPharma's control over Caraco's operations. *Id.* Movens held weekly, and eventually daily, meetings with Caraco employees to discuss quality problems, such as tablet variation, as corroborated by CW 4, CW 5, CW 6, and CW 8. ¶¶93-94, 96, 103, 164. "Corroboration from multiple sources also supports an inference of scienter." *In re Countrywide Fin. Corp. Derivative Litig.*, 554 F. Supp. 2d 1044, 1058 (C.D. Cal. 2008); *Tellabs II*, 513 F.3d at 712; *Cabletron*, 311 F.3d at 29-30.[25] Plaintiffs describe the CWs in the complaint with sufficient

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("Defendants' argument that even more detail be required, before there is any discovery, here amounts to requiring plaintiffs to plead evidence."). Nevertheless, plaintiffs have adequately alleged specifics concerning the reports defendants received or had access to, including their origins, contents, recipients, when the reports were generated and how this information was sent to defendants. ¶¶91(e), 97(b).

[24] Defendants argue that the statements of confidential witnesses are irrelevant if they were not employed during the entire Class Period. Motion at 23. On the contrary, courts recognize that "both post-class-period data and pre-class data could be used to confirm what a defendant should have known during the class period because [a]ny information that sheds light on whether class period statements were false or materially misleading is relevant." *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 249 n.13 (3d Cir. 2009); *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001); *Cornwell v. Credit Suisse Group*, No. 08 Civ. 3758(VM), 2010 WL 537593, at *7 (S.D.N.Y. Feb. 11, 2010); *In re Syncor Int'l. Corp. Sec. Litig.*, 327 F. Supp. 2d 1149, 1160 (C.D. Cal. 2004), *aff'd in part, rev'd in part and remanded on other grounds*, 239 Fed. Appx. 318 (9th Cir. Jun. 12, 2007).

[25] Defendants argue for dismissal by challenging the veracity of some the CWs and by characterizing the allegations based upon the CWs as "non-credible." Motion at 3. For instance, defendants claim that "CW7's statement is simply not believable." Motion at 25. At this stage, however, all of plaintiffs' factual allegations as pled must be taken as true. *Tellabs*,

particularity to support the probability that persons in the positions occupied by the sources would possess the information alleged. ¶¶90-98. Additionally, as described above, the statements attributed to the CWs are indicative of scienter. *Id.* Thus, the CWs "are numerous and consist of persons who from the description of their jobs were in a position to know at first hand the facts to which they are prepared to testify...." *Tellabs II*, 513 F.3d at 712; *Cabletron*, 311 F.3d at 28-31. Thus, the allegations based upon the information from CWs adds to the strong inference of scienter alleged. *Amgen*, 544 F. Supp. 2d at 1033.[26]

3. The Proximity of Defendants' Positive Statements to the Revelation of the Truth Supports a Strong Inference of Scienter

Like numerous circuit courts around the country, the Sixth Circuit holds that the "temporal proximity" between defendants' falsehoods and subsequent disclosures can help bolster a strong inference of scienter. *Helwig*, 251 F.3d at 552 ("closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent

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127 U.S. at 326. Courts "will not entertain a challenge to the credibility of confidential witnesses." *In re NPS Pharms, Inc. Sec. Litig.*, 2007 WL 1976589, at *5 (D. Utah July 3, 2007).

[26] Citing *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753 (7th Cir. 2007), defendants claim that the Court must discount allegations based upon confidential witnesses. Motion at 22. The Seventh Circuit, however, limited the scope of *Higginbotham* in *Tellabs II*. *Tellabs II* "apparently circumscribes *Higginbotham*'s broad pronouncement that confidential witness allegations will 'usually' be steeply discounted, clarifying that the weight accorded to anonymous sources will depend in large part on the level of detail with which they are described." 564 F.3d at 262. Thus, numerous courts have rejected Defendants' suggestion (Motion at 22) that CWs may have personal motives that may undermine credibility and have continued "to consider allegations based on information provided by confidential sources without discounting those allegations due ***solely*** to the anonymity of the information's source." *In re PXRE Group, Ltd. Sec. Litig.*, 600 F. Supp. 2d 510, 526 n.18 (S.D.N.Y. 2009) (emphasis in original); *City of Brockton Ret. Sys. v. Shaw Group, Inc.*, 540 F. Supp. 2d 464, 474 (S.D.N.Y. 2008); *Amgen*, 544 F. Supp. 2d at 1032-33 (C.D. Cal. 2008); *Huffy*, 577 F. Supp. 2d at 991-93; *Silverman v. Motorola, Inc.*, No. 07 C 4507, 2008 WL 4360648, at *14 (N.D. Ill. Sept. 23, 2008); *Lefkoe v. Jos. A. Bank Clothiers*, Civil No. WMN-06-1892, 2008 WL 7275126, at *6-*7 (D. Md. May 13, 2008); *Schleicher v. Wendt*, 529 F. Supp. 2d 959, 972 (S.D. Ind. 2007). Additionally, defendants' assertion that the Court should not accord much weight to the information provided by the CWs because it is "vague and conclusory" (Motion at 23, 25) is wrong for two reasons. First, the CWs provide extremely detailed information illustrating defendants' scienter. ¶¶90-98. Second, "[v]ague or ambiguous allegations are now properly considered as a part of a holistic review when considering whether the complaint raises a strong inference of scienter." *South Ferry*, 542 F.3d at 784. Defendants, moreover, cite no authority for their contention that the CWs statements should be disregarded because they purportedly did not report concerns to the FDA. Motion at 26-27.

information" is one of the "fixed constellations of facts that courts have found probative of securities fraud"); *see also Ezra Charitable Trust v. Tyco Int'l., Ltd.*, 466 F.3d 1, 9 (1st Cir. 2006) ("Plaintiffs are correct that a short time period between an alleged misstatement and a later disclosure of inconsistent information may be relevant to the question of scienter."); *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 698 (5th Cir. 2005) (auditors' resignations within "three to four months," and company's bankruptcy "a mere eight months" following misleading press releases, were both "so temporally connected" to the releases); *Shaw*,82 F.3d at 1224) ("we need not turn a blind eye to the obvious: the proximity of the date of the allegedly fraudulent statements and omissions to both the end of the quarter then in progress and the date on which disclosure was eventually made").

Here, the temporal proximity between defendants' false and misleading statements and the disclosure of the truth also contributes to a strong inference of scienter. For example, Caraco's FY 2008 marked the Company's sixth consecutive year of exponential sales growth. ¶50. Defendants highlighted sales increasing 199% to a record $350 million. *Id.* And yet, during this same time period, the FDA issued a Form FDA 483, cautioning the Company about defective tablets, as well as the lack of internal controls. ¶59. In fact, just weeks after the FDA issued one of its Warning Letter to Caraco, Defendant Shanghvi touted Caraco's business and regulatory compliance. ¶108. Although the Company told shareholders it initiated a voluntary recall in April of 2009, FDA documents indicate the recall was "FDA Initiated" instead of "voluntary." ¶128. On May 28, 2009, Defendant Movens stated "there were no deficiencies identified during the FDA inspection in the Quality Control Laboratory which supports and tests all of our products before they are released to the market." ¶129. In fact, on June 15, 2009, the Company stated it believed it was "substantially cGMP compliant." ¶161. Just days later, the United States Attorney for the Eastern District of Michigan filed a Forfeiture Complaint alleging that the Company was still in continuing and significant violation of cGMP. ¶161. On June 25, 2009, federal agents raided the Company's

Michigan facilities to seize products manufactured by Caraco and ingredients used by the Company in manufacturing its products, sending its stock plummeting nearly 43%. ¶¶134-36.

Defendants offer no explanation for Caraco's sudden change of fortunes that would permit this Court to infer a more compelling innocent explanation for the inconsistency in defendants' statements over such a brief period of time. Motion at 17-18; *Avaya*, 564 F.3d at 272. No new, unexpected facts impacted Caraco. Thus, the closeness in time between these patently inconsistent disclosures with defendants' earlier false statements bolsters a strong inference of scienter. *Helwig*, 251 F.3d at 552; *Bridgestone*, 399 F.3d at 684; *Shaw*, 82 F.3d at 1224. [27]

4. Because the Facts Allege Relate to the Company's Core Operations, They Support a Strong Inference of Scienter

Because the facts alleged relate to the Company's core operations, they support a strong inference of scienter. When coupled with other facts, "facts critical to a business's core operations or an important transaction are so apparent that their knowledge may be attributed to the company and its key officers." *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 785-86; *Avaya*, 564 F.3d at 268-73. Indeed, "the more central a fact is to a company's core operations the more likely its executive acted with scienter." *Huffy*, 577 F. Supp. 2d at 1000. This principle applies here. Movens, as the Company's CEO, and Shanghvi, as its Chairman of the Board, are charged with knowledge of regular reports concerning Caraco's cGMP. ¶¶91, 163-69. Both men spoke to the market, holding themselves out as the

[27] Defendants contend that the Company's hiring of outside consultants to audit various areas of the Company negates any inference of scienter. Motion at 28. Courts, however, have rejected such arguments. *See, e.g., Able*, 2008 WL 1967509, at *8, *30 (finding a strong inference of scienter alleged despite the company's hiring of an outside consultant to address FDA regulatory issues); *In re Nextcard, Inc. Sec. Litig.*, 2006 WL 708663, at *5 (N.D. Cal. Mar. 20, 2006) ("The Court is not persuaded by Defendants' argument that the certification of the company's financials by its outside auditor ... negates or weakens the inference of scienter."); *In re SeeBeyond Tech. Corp. Sec. Litig.*, 266 F. Supp. 2d 1150, 1168-69 (C.D. Cal. 2003) (rejecting defendants' argument that "plaintiffs' allegations negate an inference of scienter because E&Y certified the financial statements containing the [company's] revenue."); *Marksman Partners, L.P. v. Chantal Pharm. Corp.*, 927 F. Supp. 1297, 1314 n.13 (C.D. Cal. 1996) ("The fact that Chantal's independent auditor may have approved the accounting methods will not shield Chantal from liability for deception such methods may have caused.").

executives with intimate knowledge of Caraco's business. ¶¶27-28, 170. Both Movens and Shanghvi reassured investors with specifics on the same discrete subjects that which they repeatedly discussed internally and which were critical to the Company's viability. That both men were at the pinnacle of Caraco's corporate structure and were focused upon these core issues for the Company bolsters the strong inference of their access and knowledge:

> And at the top of the corporate pyramid sat [the company's] CEO.... Almost all the false statements that we quoted emanated directly from him. Is it conceivable that he was unaware of the problems of his company's two major products and merely repeating lies fed to him by other executives of the company? It is conceivable, yes, but it is exceedingly unlikely.

Tellabs II, 513 F.3d at 711; *Miss. Pub. Employees Ret. Sys. v. Boston Sci. Corp.*, 523 F.3d 75, 91-92 (1st Cir. 2008) (strong scienter inference arises, in part, from fact executive was "point person" on new product and "would presumably have been aware" of its status). Accordingly, because the facts alleged relate to the Company's core operations, they support a strong inference of scienter. *Huffy*, 577 F. Supp. 2d at 1000.[28]

5. The Resignation of the Company's Key Executives Near the Time of the Company's Revelation of the Truth Supports a Strong Inference of Scienter

The abrupt resignation of Caraco's top executive, linked temporally to the FDA forfeiture that rocked Caraco's investors, adds to an inference of scienter. As courts have recognized, "the timing of Defendants' departures might suggest that the Company believed Defendants had been involved in wrongdoing with respect to corporate finances." *In re*

[28] Defendants' contention that plaintiffs cannot assert a claim against Shanghvi as Chairman of the Board of Directors is incorrect. Plaintiffs do not assert that Shanghvi is liable merely because of his position, but because he actually made false statements while in possession of contradictory information. ¶¶28-29, 108-9. Courts have held that directors face liability under these circumstances. *Cabletron*, 311 F.3d at 41; *Howard v. Everex Sys.*, 228 F.3d 1057, 1061-62 (9th Cir. 2000). Additionally, while defendants attempt to distance defendant Shanghvi from the statement alleged (¶108) by arguing that the statement is unclear (Motion at 34), defendants ignore that "[w]hen an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." *Helwig*, 251 F.3d at 553. Moreover, defendants ignore the statement's reference to "USFDA" when, as set forth in the Complaint, Caraco was viewed as "Sun Pharma's U.S. presence" and its "U.S. subsidiary." ¶53. Contrary to defendants' arguments, moreover, Sun Pharma faces liability under Section 10(b) based upon its reckless disregard of Caraco. *In re Alstom SA*, 454 F. Supp. 2d 187, 200 (S.D.N.Y. 2006); *In re Marsh & McLennan Co. Inc. Sec. Litig.*, No. 04 CV 8144, 2006 WL 2057194, *24 (S.D.N.Y. July 20, 2006).

UTStarcom, Inc. Sec. Litig., 617 F. Supp. 2d 964, 976 (N.D. Cal. 2009); *ASG*, 2009 WL 1348163, at *58; *In re Impax Laboratories, Inc. Sec. Litig.*, 2007 WL 7022753, at *9 (N.D. Cal. July 18, 2007)*(rev'd on other grounds,*2008 WL 1766943 (N.D.Cal. Apr. 17, 2008); *In re Adaptive Broadband Sec. Litig.*, No. C 01-1092 SC, 2002 WL 989478, at *14 (N.D. Cal. Apr. 2, 2002); *In re McKesson HBOC Inc. Sec. Litig.*, 126 F. Supp. 2d 1248, 1274 (N.D. Cal. 2000). Indeed, even where a resignation "was not accompanied by an extraordinary punishment" it can be "highly probative of scienter." *Middlesex Ret. Sys. v. Quest Software, Inc.*, No. CV 06-6863 DOC (RNBx), 2008 WL 7084629, at *9 (C.D. Cal. July 10, 2008).[29]

Movens was Caraco's CEO, and primarily responsible for the day-to-day operations of the Company. ¶27. Moreover, on September 20, 2009, George Ugeux, an independent director of Caraco's board resigned. Ugeux said that he resigned because of "management and the majority shareholder's absolute refusal to permit a focused independent look at corporate governance matters to determine if they contributed to the events leading up to the FDA seizure." ¶141. Given these case-specific facts, Movens and Ugeux's departures add to the strong inference of scienter alleged. When departures are linked to financial shenanigans, or complement other additional facts, the sudden resignations add to the inference of scienter alleged. *ASG*, 2009 WL 1348163, at *58.

6. Defendants' Self Motivation in Saving Their Salaries and Bonuses Supports a Strong Inference of Scienter

As the Sixth Circuit has declared, "self-interested motivation of defendants in the form of saving their salaries" can support a strong inference of scienter. *Helwig*, 251 F.3d at 552; *Bridgestone*, 399 F.3d at 687. This motivation existed with Movens and Shanghvi. For example, in 2008, Daniel Movens made $875,718, which included a $150,478 bonus and a $427,596 salary. He also received a stock award valued at $119,250. Movens and Shanghvi also personally benefitted from their fraudulent conduct as they stood to gain millions of

[29] *See also In re Scottish Re Group Sec. Litig.*, 524 F. Supp. 2d 370, 394 n.176 (S.D.N.Y. 2007); *In re Nash Finch Co.*, 502 F. Supp. 2d at 882; *Kaltman v. Key Energy Services, Inc.*, 447 F. Supp. 2d 648, 664 (W.D. Tex. 2006).

dollars in stock options or other compensation that was directly linked to Caraco's reported net income. Defendants, moreover, need not reap concrete and personal benefits before any scienter inference arises. Indeed, one district court in the Sixth Circuit has rejected the "concrete and personal" contention due to the fact that it imposes a higher standard than necessary under *Tellabs*. *See Huffy*, 577 F. Supp. 2d at 991 (rejecting defendants' concrete and personal benefit argument because inference of scienter only requires fraudulent acts be at least as compelling as non-fraudulent acts).

Additionally, the fraud-linked benefits need not be realized; it is the ***expectation*** of that realization that helps raise a strong inference of scienter. *PR Diamonds*, 364 F.3d at 690; *see also Tellabs II*, 513 F.3d at 710 (defendants' excuse that no one ultimately profited from the fraud "confuses expected with realized benefits"); *Florida State Bd. Of Admin v. Green Tree Fin. Corp*, 270 F.3d 645, 662 (8th Cir. 2001) ("The ultimate profitability of a course of conduct is not conclusive of intent."). In sum, Caraco's reaping of benefits, and Movens and Shanghvi's expectation of reaping benefits, are among the facts adding to the strong inference of scienter. *In re Telxon Corp. Sec. Litig.*, 133 F. Supp. 2d 1010, 1028 (N.D. Ohio 2000) (courts "must consider allegations of motive and opportunity in conjunction with the remainder of plaintiffs' allegations to determine whether the allegations, on the whole, raise an inference of recklessness or knowing disregard").[30]

[30] Defendants contend that the lack of stock sales negates any inference of scienter. Motion at 30-31. However, "the absence of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 325. Thus, "[s]cienter can be established even if the officers who made the misleading statements did not sell stock during the class period." *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 944 (9th Cir. 2003); *Siracusano*, 585 F.3d at 1182-83; *PR Diamonds*, 364 F.3d at 691; *Pirraglia*, 339 F.3d at 1191 n.12. Defendants also assert that Sun Pharma's increase of beneficial ownership of Caraco during the Class Period negates any inference of scienter. Motion at 30-31. Courts, however, reject a general holding that an increase in stock ownership negates an inference of scienter. *Holmes v. Baker*, 166 F. Supp. 2d 1362, 1378 (S.D. Fla. 2001); *see also In re Thornburg Mortg., Inc. Sec. Litig.*, No. CIV 07-0815 JB/WDS, 2010 WL 378300, at *22-*23 (D.N.M. Jan. 27, 2010) (rejecting defendants' argument that their purchase of $25 million worth of company securities during the class period negates any inference of scienter); *In re Ashanti Goldfields Sec. Litig.*, No. CV 00-0717 (DGT), 2004 WL 626810, at *5 (E.D.N.Y. Mar. 30, 2004) ("net purchases of stock by defendants do not necessarily negate an inference of

7. The Company's Signed Certifications to the Securities and Exchange Commission Add to the Strong Inference of Scienter Alleged

The Company's SOX certifications are yet another factor adding to the scienter inference. Combined with other scienter allegations, SOX certifications can support a strong inference of actual knowledge or deliberate recklessness. *See, e.g., Proquest* 527 F. Supp. 2d at 742-43 ("The SOX certifications give rise to an inference of [defendant's] scienter"); *Backe v. Novatel Wireless, Inc.*, 607 F. Supp. 2d 1145, 1163 (S.D. Cal. 2009) (holding that "false SOX certifications are relevant to scienter"); *Rosky ex rel. Wellcare Health Plans, Inc. v. Farha*, No. 8:07-cv-1952-T-26MAP, 2009 WL 3853592, at *6 (M.D. Fla. Mar. 30, 2009) ("Defendants' false Sarbanes-Oxley certifications also support a strong inference of scienter."). [31] SOX certification requirements were ***expressly designed*** to prevent top executives from adopting a "head in the sand" defense, as defendants have done here, to actions for securities fraud committed on their watch. The SEC recognized as much in implementing §302, by expressly warning corporate officers that "a false certification potentially could be subject to ... both Commission and private actions for violating Section 10(b) of the Exchange Act and Exchange Act Rule 10b-5." SEC Act Release No. 8124, Pt. II.B.6, 2002 WL 31720215, at *9 (Aug. 28, 2002) (also available at www.sec.gov/rules/final/33-8124.htm).[32]

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scienter"); *SeeBeyond*, 266 F. Supp. 2d at 1169 (rejecting defendants' argument that "purchases of stock negate an inference of scienter").

[31] *See also ASG*, 2009 WL 1348163, at *52-*53; *Stocke v. Shuffle Master, Inc.*, 615 F. Supp. 2d 1180, 1190-91 (D. Nev. 2009); *Middlesex Ret. Sys. v. Quest Software*, 527 F. Supp. 2d 1164, 1189-90 (C.D. Cal. 2007); *Wieland v. Stone Energy Corp.*, No. 05-2088, 2007 WL 2903178, at *7 (W.D. La. Aug. 17, 2007); *In re OCA, Inc. Sec. and Derivative Litig.*, No. 05-2165, 2006 WL 3747560, at *22 (E.D. La. Dec. 14, 2006); *Croker v. Carrier Access Corp.*, Civil Case No. 05-cv-01011-LTB-OES, 2006 WL 2038011, at *11 (D. Colo. July 18, 2006); *In re Lattice Semiconductor Corp. Sec. Litig.*, No. CV04-1255-AA, 2006 WL 538756, at *17-*18 (D. Or. Jan. 3, 2006).

[32] Plaintiffs are not alleging, as defendants suggest, that SOX certifications ***alone*** raise an inference of scienter. This is yet another attempt by defendants to get this Court to isolate individual allegations rather than consider the totality of the circumstances as required in this Circuit. *See P.R. Diamonds*, 364 F.3d at 683. As the Sixth Circuit has declared, "we cannot disregard any set of facts as insufficient as a matter of law." *Helwig*, 251 F.3d at 551-52.

Through the SOX certifications, CEO Movens attested that adequate control procedures were in place. ¶¶27, 170. With these certifications, CEO Movens represented that he had personally reviewed the Company's SEC filings and that, based on his personal knowledge, none of the information contained within them was false or misleading. *Id.* To further assure investors of the statements' accuracy, Movens certified that his was personally responsible for establishing and maintaining Caraco's disclosure controls and procedures. *Id.* Movens also attested that he had evaluated the effectiveness of Caraco's disclosure controls and procedures. Each of these certifications was false and misleading and thus provide additional evidence bolstering a strong inference of scienter. *Proquest*, 527 F. Supp. 2d at 742-43.

Collectively considered, as required, plaintiffs' allegations raise a strong inference of scienter. Defendants offer no more compelling inferences. As such, plaintiffs' complaint should be permitted to move forward. *See Frank*, 547 F.3d at 571 (quoting *ACA Fin.*, 512 F.3d at 59 ("*Tellabs* now awards the draw to the plaintiff.")).[33]

E. Plaintiffs Adequately Allege Control Person Liability

Defendants assert that the Court must dismiss plaintiffs' control person claim under Section 20(a) of the Exchange Act for three reasons: (1) plaintiffs purportedly have not pled a primary violation under Section 10(b); (2) plaintiffs purportedly have not pled sufficient facts

[33] Defendants contend that the group published pleading doctrine did not survive passage of the PSLRA Motion at 32. Although plaintiffs state facts with respect to defendants' scienter individually, the vast majority of the courts that have considered the group published pleading doctrine after the passage of the PSLRA have held that the doctrine is indeed viable. *See, e.g., In re Semgroup Energy Partners, L.P.*, No. 08-MD-1989-GKF-FHM, 2010 WL 1816434, at *13 (N.D. Okla. Apr. 30, 2010) ("district courts in the Tenth Circuit continue to hold that the doctrine remains viable"); *The Pennsylvania Avenue Funds v. Inyx Inc.*, No. 08 Civ. 6857(PKC), 2010 WL 743562, at *10 n.3 (S.D.N.Y. Mar. 1, 2010) ("The majority of judges in this district who have addressed the issue have concluded that the group pleading doctrine has survived the PSLRA."); *In re Williams Sec. Litig.*, 339 F. Supp. 2d 1242, 1260 (N.D. Okla. 2003) ("a majority of the district courts addressing the issue have found that the group pleading doctrine survives the PSLRA."); *In re Secure Computing Corp. Sec. Litig.*, 120 F. Supp. 2d 810, 821-22 (N.D. Cal. 2000) ("Moreover, the majority of the district courts in the Ninth Circuit that have addressed the issue have concluded that the group published information presumption survives the PSLRA.").

demonstrating that defendants exercised control over a primary violator; and (3) plaintiffs purportedly have not demonstrated that defendants were culpable participants in the underlying violation. Motion at 41-44. Each of these reasons fails.

First, as demonstrated above, plaintiffs have pled a primary violation by demonstrating that plaintiffs have adequately stated a claim of securities fraud under Section 10(b) of the Exchange Act. Second, plaintiffs have also adequately alleged that defendants Movens, Shanghvi, and Sun Pharma exercised control over the Company. Specifically, plaintiffs allege that defendants Movens and Shanghvi signed numerous SEC filings and made numerous statements on behalf of the Company and "possessed the power and authority to control the contents of Caraco's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market." ¶¶27-29, 188-190. Plaintiffs also allege that defendants Movens and Shanghvi "had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company...." ¶188. Courts in this circuit have repeatedly held that such allegations are sufficient to state a claim under Section 20(a) against insiders. *ASG*, 2009 WL 1348163, at *58-*61; *Huffy*, 577 F. Supp. 2d at 1020-22; *Proquest*, 527 F. Supp. 2d at 741-42, 744, 746. Additionally, plaintiffs allege that Sun Pharma owned 76% of Caraco during the Class Period and also had the power to influence and control the Company. ¶¶3, 30, 188-190. Courts have also held that corporate entities are liable under Section 20(a) where they exercised such significant control over another entity. *See In re Mutual Funds Invest. Litig.*, 566 F.3d 111, 129-31 (4th Cir. 2009) ("a corporation may be a controlling person when it owns the majority of the shares of another corporation"); *America West*, 320 F.3d at 945-46 (holding that plaintiffs' control person allegations were sufficient against a company that controlled 57% of the controlled entity).

Finally, although defendants claim that plaintiffs have not adequately alleged culpable participation with respect to their control person claim, such allegations are not a requirement in this circuit. As one court held in rejecting this argument: "Defendants also argue that the

Plaintiffs have failed to alleged specific facts establishing culpable participation in the fraud perpetrated by the controlled person. However, when it listed the two essential elements of a claim under §20(a), in *PR Diamonds*, the Sixth Circuit did not recognize such as one of those elements. 364 F.3d at 696. Therefore, the asserted failure of the Plaintiff to allege such facts does not serve as the basis for dismissing this claim." *Huffy*, 577 F. Supp. 2d at 1021 n.56; *see also In re National Century Fin. Enterprises, Inc. Invest. Litig.*, 504 F. Supp. 2d 287, 300-304 (S.D. Ohio 2007); *Proquest*, 527 F. Supp. 2d at 746 n.10.[34]

VI. CONCLUSION

For the foregoing reasons, the Court should deny defendants' Motion. If the Court grants any part of the Motion, plaintiffs respectfully request leave to amend the Complaint. *Huffy*, 577 F. Supp. 2d at 982 n.14.

Dated: May 27, 2010

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[34] The cases defendants cite are distinguishable. *D.E. & J Ltd. Partnership v. Conaway*, 284 F. Supp. 2d 719 (E.D. Mich. 2003), was decided before the Sixth Circuit's decision in *PR Diamonds*, which established that culpable participation is not a requirement under Section 20(a) in this circuit. *PR Diamonds*, 364 F.3d at 696. Additionally, *Mishkin v. Ageloff*, No. 97 Civ. 2690 LAP, 1998 WL 651065 (S.D.N.Y. Sept. 23, 1998), is a district court case from the Second Circuit, not the Sixth Circuit. There is a split of authority in the Second Circuit on the issue, with many courts holding after *Mishkin* that claims under Section 20(a) do not require allegations of culpable participation. *In re Parmalat Sec. Litig.*, 497 F. Supp. 2d 526, 532 n.42 (S.D.N.Y. 2007); *In re WorldCom, Inc. Sec. Litig.*, 294 F. Supp. 2d 392, 415 (S.D.N.Y. 2003); *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 396 (S.D.N.Y. 2003).

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CERTIFICATE OF SERVICE

I, E. Powell Miller, hereby certify that on May 27, 2010, I electronically filed the foregoing **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** with the Clerk of the Court using the ECF System which will send notification of such filing to the following:

See Attached Service List.

There are no non-ECF participants in this action.

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